

### **REMARKS**

After entry of this amendment, claims 1-14 and 64-66 are pending, of which claims 7-9 are withdrawn. The claims have been amended without prejudice or disclaimer and find support *inter alia* in the original claims. No new matter has been added.

Applicants respectfully request entry of the above amendments because the finality of the present Action is inappropriate for the reasons discussed below in the section entitled "Finality of the Present Action." Alternatively, Applicants also believe that the above amendments should be entered under 37 CFR §1.116 practice because the above amendments put the claims in condition for allowance or, alternatively, in better form for consideration on appeal by further narrowing the scope of the claims. The above amendments also do not present any new issues that require further consideration or search. Accordingly, entry under 37 CFR §1.116 is correct.

#### **Finality of the Present Action**

Applicants respectfully request that the finality of the present action be withdrawn because the finality of the present Office Action is inappropriate for at least the following reasons.

In the present Action, the Examiner rejects the claims based on two new grounds of rejections, i.e. a new ground of rejection under 35 U.S.C. § 112, first paragraph, alleging that the claims lack adequate written support and a new ground of rejection under 35 U.S.C. § 112, first paragraph, alleging that the specification does not provide enablement for the claimed subject matter. Pursuant to MPEP § 706.07(a), a second or any subsequent action on the merits in any application will not be made final if it includes a new ground of rejection that is neither necessitated by applicant's amendment of the claims, nor based on information submitted during the period set forth in 37 C.F.R. § 1.97(c). As discussed in more detail below, the new rejections were not necessitated by Applicants' amendment of the claims and thus, are new grounds of rejection in the present Action. For at least this reason, the action should not have been made final.

Moreover, Applicants respectfully disagree that the new rejections were necessitated by Applicants' amendment of the claims as alleged by the Examiner. The amendment to former claim 1 further narrows the scope of the claimed genus of polypeptides with  $\Delta 5$ -elongase

activity. Without acquiescing to the rejection, if the genus as amended lacked adequate written support as alleged by the Examiner, the genus prior to the amendment would also have lacked adequate written support. Similarly, if the claims as amended are not enabled by the present specification, the claims prior to the amendment would also not be enabled by the same specification. Accordingly, both new grounds of rejection under 35 U.S.C. § 112, first paragraph, could have been made prior to the previous amendments and as such were not necessitated by Applicants' amendment to the claims. For this additional reason, the finality of the present Office Action was improper and should be withdrawn.

### **Rejoinder Request**

Applicants respectfully request rejoinder of withdrawn claims 7-9 for the following reasons.

Withdrawn claims 7-9 depend directly from claim 1 and as such, further narrow the scope of the base claim. For example, claim 7 is drawn to a process for the production of compounds of the general formula I as recited in claim 1, wherein the process further comprises introducing a nucleic acid sequence encoding a polypeptide with  $\omega$ 3-desaturase activity. Similarly, claim 8 is drawn to a process for the production of compounds of the general formula I as recited in claim 1, wherein the process further comprises introducing a nucleic acid sequence encoding a polypeptide with  $\Delta$ 12-desaturase activity. Likewise, claim 9 is drawn to a process for the production of compounds of the general formula I as recited in claim 1, wherein the process further comprises introducing a nucleic acid sequence encoding a protein of fatty acid or lipid metabolism biosynthetic pathway. Thus, the subject matter of claim 1 and the subject matter of withdrawn claims 7-9 are related and not independent because they are disclosed as connected in at least one design, operation, or effect. Accordingly, restriction between these claims would be improper.

Moreover, because these withdrawn claims are drawn to the same subject matter as recited in claim 1, Applicants believe that there would be no extra burden on the Examiner to consider these claims together with claim 1 in the present application.

For at least the above reasons, Applicants respectfully request reconsideration and rejoinder of withdrawn claims 7-9.

### **Claim Objections**

Claim 64 is objected to for missing the term “bond” in the recitation of “with one double in.” In response, claim 64 has been amended without prejudice or disclaimer by adopting the Examiner’s suggestion. Applicants believe that the present amendment overcomes the objection. Withdrawal of the objection is therefore respectfully requested.

Claim 6 is objected to for reciting non-elected sequences, namely SEQ ID NO: 53 (encoding SEQ ID NO: 54) and SEQ ID NO: 113 (encoding SEQ ID NO: 114), both encode a polypeptide with  $\Delta 5$ -elongase activity. Applicants respectfully disagree for the reasons already of record. Because the election to the sequences that correspond to the elected subject matter is for search purposes only, i.e. species election, as previously acknowledged by the Examiner, Applicants respectfully request rejoinder of the non-elected species upon allowance of the generic claim or the claims directed to the elected species. 37 CFR § 1.141; MPEP § 809.02(a).

### **Double Patenting**

Claims 1-6, 10-14 and 64-66 are provisionally rejected for obviousness-type double patenting over claims 1, 2 and 5-11 of co-pending Application No. 10/566,944. Because this is a provisional double patenting rejection, Applicants will consider filing an appropriate terminal disclaimer upon an indication that the claims are allowable.

### **New Claim Rejections – 35 U.S.C. § 112**

Claims 1-6, 10-14 and 64-66 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement and for alleged lack of an enabling disclosure. Applicants respectfully disagree and traverse the rejections.

#### ***Written Description Rejection***

Claims 1-6, 10-14 and 64-66 are newly rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of written description support.

The Examiner notes that the specification discloses three  $\Delta 5$ -elongases having the recited activity, i.e. elongates only unsaturated C20-fatty acids, when expressed in yeast. The Examiner further notes that the specification discloses another  $\Delta 5$ -elongase isolated from *Ostreococcus tauri* having the recited activity when expressed in a plant, but alleges that it is unclear from the

specification which sequences are presented in the pSUN-8G construct that was transformed into Brassica plants. The Examiner additionally notes that the specification discloses about 20 additional  $\Delta 5$ -elongases, but alleges that they have a broader specificity. The Examiner thus concludes that the specification does not provide any distinguishing structural features that define the claimed functional genus and thus, fails to satisfy the written description requirement. Applicants respectfully disagree.

The “written description” requirement under 35 U.S.C. § 112, first paragraph, serves both to satisfy the inventor’s obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed. *Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1084 (Fed. Cir. 2005); *see also* MPEP § 2163. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was “ready for patenting” such as by the disclosure of structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. *See* MPEP § 2163 (citation omitted).

A written description of an invention involving a nucleic acid, like a description of a chemical genus, “requires a precise definition, such as by structure, formula, [or] chemical name,” of the claimed subject matter sufficient to distinguish it from other materials. *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993). For a claimed genus, the written description requirement may be satisfied through sufficient description of a representative number of species by actual reduction to practice, by disclosure of relevant identifying characteristics, by functional characteristics coupled with known or disclosed correlation between function and structure, or by a combination of such identifying characteristics. *See Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997).

As described in the specification, two types of  $\Delta 5$ -elongases exist, multifunctional elongases and monofunctional elongases. Specification at page 41, line 34, through page 42, line 25. The  $\Delta 5$ -elongases found in human and non-human animals, such as *Oncorhynchus mykiss*, *Xenopus laevis*, and *Ciona intestinalis*, are demonstrated to be multifunctional elongases, which convert a broad substrate spectrum. *See e.g.*, Specification at page 42, lines 8-10 and 27-30, and Figure 27. In contrast, the  $\Delta 5$ -elongases from, for example, *Thallasiosira pseudonana* and

*Ostreococcus tauri*, are demonstrated to be monofunctional elongases, which convert only C20-fatty acids. See e.g., Specification at page 42, lines 33-37, and Figure 28. The preferred  $\Delta 5$ -elongases for the use in the process according to the present application are those monofunctional elongases as recited in the present claims.

As noted by the Examiner, the specification provides a total of twenty-four  $\Delta 5$ -elongases in Table 1 at pages 16-18. However, contrary to the Examiner's assertion, only four  $\Delta 5$ -elongases among those exemplified are shown to be multifunctional elongases having a broader specificity (i.e. SEQ ID NO: 51 and 53 from *Oncorhynchus mykiss*, SEQ ID NO: 117 from *Xenopus laevis*, and SEQ ID NO: 119 from *Ciona intestinalis*; see e.g. Figure 27). Discounting those multifunctional  $\Delta 5$ -elongases, the specification still provides at least twenty  $\Delta 5$ -elongases from various species, including *Thalassiosira pseudonana*, *Cryptocodinium cohnii*, *Thraustochytrium aureum*, *Ostreococcus tauri*, *Euglena gracilis*, and *Arabidopsis thaliana*, which the Examiner characterizes to also have a broader specificity. Office Action at page 6. Applicants strongly disagree. It is noted initially that the Examiner points to no evidence to support such as assertion. It is further noted that, according to the specification, in addition to the  $\Delta 5$ -elongases from *Ostreococcus tauri* and *Thalassiosira pseudonana*, at least the  $\Delta 5$ -elongases from *Arabidopsis thaliana* and *Euglena gracilis* are also distinguished by their specificities. Specification at page 43, lines 2-3. Thus, it is respectfully submitted that the specification discloses at least 20 species of the claimed genus, which are sufficiently representative of the claimed genus absent evidence to the contrary.

Moreover, as also noted by the Examiner, the specification demonstrates three  $\Delta 5$ -elongases having the recited activity when expressed in yeast, i.e. OtELO1 (SEQ ID NO: 67), OtELO1.2 (SEQ ID NO: 113), and TpELO1 (SEQ ID NO: 43), by working examples. The specification further shows that the  $\Delta 5$ -elongase from *Ostreococcus tauri* also possesses the recited activity. As described in the specification, the construct pSUN-8G was generated to include the sequences of SEQ ID NO: 41, 53, 87 and 113, of which SEQ ID NO: 113 encodes a  $\Delta 5$ -elongase from *Ostreococcus tauri*. Specification at page 171, lines 13-17. Analysis of the LCPUFAs produced in the plants transformed with the construct pSUN-8G confirms that this  $\Delta 5$ -elongase from *Ostreococcus tauri* possesses the recited specificity. See Example 61 at page 176, Figure 32, and Table 24. Thus, the specification demonstrates, by actual reduction to

practice, that at least four of the aforementioned  $\Delta 5$ -elongases have the recited activity. Since there has never been an requirement that every species encompassed by a claim must be disclosed or exemplified in a working example, *see In re Angstadt*, 537 F.2d 498 (CCPA 1976), Applicants respectfully submit that the twenty species disclosed in the present specification, including four demonstrated by working examples, are sufficiently representative of the claimed genus and thus, satisfies the written description requirement under the standard of *Regents v. Lilly*.

For at least the above reasons, it is respectfully submitted that the specification provides adequate written description for the present claims. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

#### ***Enablement Rejection***

Claims 1-6, 10-14 and 64-66 are newly rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of an enabling disclosure.

Similar to the written description rejection, the Examiner contends that the specification does not set forth any distinguishing structural features that define the claimed functional genus. The Examiner further asserts that the specification appears to provide only one example of  $\Delta 5$ -elongase having the claimed activity in plant. The Examiner thus concludes that undue experimentation would be required to make and/or use the claimed process. Applicants respectfully disagree.

It is noted initially that the disclosure provided in the specification is presumptively enabling. The manner of making and using the claimed invention must be taken as in compliance with the first paragraph of 35 U.S.C. § 112, unless there is objective evidence or scientifically based reasoning inconsistent with the specification. *See In re Marzocchi and Horton*, 169 U.S.P.Q. 367 (C.C.P.A. 1971). "It is the Patent Office's burden to present evidence that there is some reason to dispute the enablement provided in the specification. Unsupported speculation or conjecture on that the invention 'might not work' will not support a rejection based on 35 U.S.C. § 112, first paragraph." *Id.* Simply pointing to the absence of a working example provides neither objective evidence nor reasoning in support of the rejection, and accordingly, a *prima facie* case of non-enablement on this ground has not been made out. Moreover, there has never been a requirement that every species encompassed by a claim must

be disclosed or exemplified in a working example. *In re Angstadt*, 537 F.2d 498 (CCPA 1976). Additionally, even though practicing the full scope of the claims might have required some amount of experimentation, if the experimental techniques are well-known in the art, the experimentation is routine and not undue. See *Ex parte Kubin*, 83 USPQ2d 1410 (B.P.A.I. 2007), *aff'd on other ground*, 90 USPQ 2d 1417 (Fed. Cir. 2009).

As discussed above, the specification provides at least twenty  $\Delta 5$ -elongases from various species, of which four are shown to have the recited activity by working examples and more are described to be distinguished by their specificities. Additionally, the specification further provides in detail, by way of working examples, how to isolate a  $\Delta 5$ -elongase gene from various species (e.g., Examples 10, 14, 19, 43, and 48), how to clone and overexpress such a gene in yeast (e.g., Examples 11, 15, 20, 44, and 49), and how to determine the effect of such an overexpression in yeast (e.g., Examples 13, 18, 23, 47, and 51). Thus, one skilled in the art would be able to identify a  $\Delta 5$ -elongase having the recited specificity without undue experimentation.

Moreover, the specification further describes, in detail, how to clone various genes in plasmid for expression in plants (e.g., Examples 12, 16, 21, 45, and 57), how to generate transgenic plants expressing various genes of fatty acid biosynthesis pathway (e.g., Example 58), and how to determine the effect of such an overexpression in the seeds of transgenic plants (e.g., Examples 60 and 61). Although the specification exemplifies only a few  $\Delta 5$ -elongases with the recited activity in the working examples, Applicants respectfully submit that these procedures and techniques are equally applicable to other  $\Delta 5$ -elongase genes, including those exemplified in Table 1.

Thus, in view of the detailed description, guidance, working examples, and high level of skill, the specification enables the full scope of the present claims without undue experimentation. Additionally, even if we are to assume that the amount of experimentation to practice the full scope of the claimed invention might be extensive, as found by the Board in *Ex parte Kubin*, such experimentation would have been routine, and not undue experimentation. See *Ex parte Kubin*. Compare, *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (routine screening of hybridomas was not “undue experimentation;” the involved experimentation can be

considerable, so long as "routine"). On these facts, an analysis under *In re Wands* supports enablement.

For at least the above reasons, it is respectfully submitted that the claims recite a scope of subject matter which a skilled artisan could clearly make and use according to the teaching in the specification. Reconsideration and withdrawal of this rejection is therefore respectfully requested.

### CONCLUSION

For at least the above reasons, Applicants respectfully request withdrawal of the rejections and allowance of the claims. If any outstanding issues remain, the Examiner is invited to telephone the undersigned at the number given below.

Applicants reserve all rights to pursue the non-elected claims and subject matter in one or more divisional applications.

This response is filed within the three-month period for response from the mailing of the Office Communication. No fee is believed due. However, if a fee is due, please charge our Deposit Account No. 03-2775, under Order No. 13987-00020-US from which the undersigned is authorized to draw.

Respectfully submitted,

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